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**From:** Epstein, Laura [Laura.Epstein@fda.hhs.gov]  
**Sent:** 1/17/2017 3:01:51 PM  
**To:** Wozniak, Chris [wozniak.chris@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]  
**Subject:** FW: Intrexon/Oxitec Meeting  
**Attachments:** removed.txt; Oxitec Pre-EUA Slides.pdf; Oxitec Pre-EUA Outline.pdf

FYI:

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**From:** Sadove, Elizabeth  
**Sent:** Tuesday, January 17, 2017 8:21 AM  
**To:** Borio, Luciana; Mair, Michael; Epstein, Laura; Beers, Donald; Zborowsky, Ashley; Dass, Brinda; Nalubola, Ritu; Flamm, Eric; Maher, Carmen; Ross, Jennifer  
**Subject:** FW: Intrexon/Oxitec Meeting

Please see message and attached from Intrexon....

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**From:** McConagha, William [mailto:wmccconagha@sidley.com]  
**Sent:** Monday, January 16, 2017 8:10 PM  
**To:** Sadove, Elizabeth  
**Cc:** Kulkarni, Deepti A.; McConagha, William  
**Subject:** Intrexon/Oxitec Meeting

Hi, Liz.

On behalf of Intrexon/Oxitec, I write to submit materials in advance of the pre-submission meeting scheduled for Thursday the 19<sup>th</sup> at 1pm.

Attached please find the slide deck we propose to present at the meeting as well as a pre-EUA submission outline based on FDA guidance for EUA submissions and the regulation of GE animals. The pre-EUA submission draws heavily on data and information previously submitted to FDA and explains how Oxitec OX513A meets the EUA standard, as described in relevant law. 21 U.S.C. § 360bbb-3, as amended by Pub. L. 114-255, § 3088 (2016).

Please let us know if you have any questions or concerns.

I look forward to seeing you Thursday.

Best regards,

-Bill

**WILLIAM A. MCCONAGHA**  
Partner

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